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10/540,394	09/01/2005	Eiji Sunahara	Q101062	4910

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EXAMINER	
DUFFY, BRADLEY	

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1643	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,394	SUNAHARA ET AL.	
	Examiner	Art Unit	
	Brad Duffy	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *1-28 and 31-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/23/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Exhibit A*.

DETAILED ACTION

1. The election with traverse filed May 15, 2007, is acknowledged and has been entered.

Applicant has elected the invention of Group XXXI, claims 29-30, directed to antibodies that specifically react with a protein comprising the same or substantially the same amino acid sequence represented by SEQ ID NO: 1.

2. Claims 1-42 are pending in the application.

3. Claims 1-28 and 31-42 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 15, 2007.

4. Claims 29-30 are under examination.

Election/Restrictions

5. Applicant's traversal of the restriction and election requirement set forth in the Office action mailed April 16, 2007, is acknowledged.

Applicant's arguments have been carefully considered but have not been found persuasive for the following reasons:

Applicant has argued that "Groups X, XI and XII should be grouped together with elected Group XXXI" and that Groups X, XI and XII are "drawn to antibodies that specifically bind a protein comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO:4, SEQ ID NO:7 or SEQ ID NO:10, respectively" (see page 1 of the response filed May 15, 2007).

In response, as explained in the preceding Office action, the inventions of Groups XXXI, X, XI and XII do not share the same technical feature, since, for example,

as Applicant has remarked, the amino acid sequences of SEQ ID NOs: 1, 4, 7, and 10 are distinct, each from the others, and the Applicant has not provided any evidence or arguments establishing that these Groups have unity of invention as required by PCT Rule 13. Furthermore, the inventions of Group XXXI include an apoptosis promoter or prophylactic/therapeutic agent for cancer comprising an antibody that binds the polypeptide of SEQ ID NO: 1; in contrast, the inventions of Groups X, XI and XII include antibodies or agents comprising such antibodies, which need not bind the polypeptide of SEQ ID NO: 1. In addition, it is aptly noted that one would not make an antibody that necessarily binds to a polypeptide comprising SEQ ID NO: 1 by immunizing an animal with a polypeptide comprising a different amino acid sequence (e.g., the amino acid sequences of SEQ ID NOs: 4, 7, and 10); and it is for the reason as well that each of the different inventions of Groups XXXI, X, XI and XII do not share the same technical feature, so as to form a single general inventive concept in accordance with PCT Rules 13.1 and 13.2.

Accordingly the restriction between the inventions of Groups XXXI, X, XI and XII is deemed proper.

Therefore, for these reasons and the reasons set forth in the Office action mailed April 16, 2007, these inventions do not share unity of invention as required under PCT Rule 13 and the restriction/election requirement is deemed proper and therefore made FINAL.

Priority

6. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

7. The references cited in the information disclosure statement filed on June 23, 2005, have been considered.

The supplemental information disclosure statement filed January 27, 2006 fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications, applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. In this case a listing of references could not be found with the submission filed January 27, 2006. If Applicant desires other references to be considered Applicant is invited to submit an information disclosure statement that complies with 37 CFR 1.98(a)(1).

Specification

8. The disclosure is objected to because of the following informalities:

(a) The specification is objected to because the use of improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

Exampled of such improperly demarcated trademarks appearing in the specification are Sepharose™ (numerous instances, see e.g., page 81, line 19) and GenBank™ (numerous instances, see e.g., page 2, line 7).

Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at <http://www.uspto.gov/web/menu/search.html>.

(b) The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 29-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 29-30 are indefinite in the recitation of "a protein comprising the same or *substantially the same* amino acid sequence as the amino acid sequence *represented by* SEQ ID NO:1 [italics added for emphasis]". Notably, the claims are indefinite because it is unclear which proteins have "substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO:1" as "substantially" is a relative that is not defined by the claim, so it is not apparent to what requisite degree a protein must be substantially the same as a protein comprising the amino acid sequence of SEQ ID NO:1, for example. Furthermore, the phrase "represented by" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. For example, it is unclear what other polypeptides SEQ ID NO:1 represents. Does SEQ ID NO:1 represent other polypeptides that have amino acid substitutions, deletions or insertions when compared to SEQ ID NO:1, any polypeptide with any amino acid sequence or just polypeptides comprising SEQ ID NO:1? See MPEP § 2173.05(d). For these reasons, the claims fail to delineate the metes and bounds of the subject matter regarded as the invention with the clarity and particularity necessary to satisfy the requirement set forth under 35

U.S.C. § 112, second paragraph, so as to permit the skilled artisan to know or determine infringing subject matter.

Amending the claims to recite that the protein comprises the amino acid sequence of SEQ ID NO:1, for example, would overcome this rejection.

Accordingly, these claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claims 29-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, ``Written Description" Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001; hereinafter "Guidelines"). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

These guidelines state that rejection of a claim for lack of written description, where the claim recites the language of an original claim should be rare. Nevertheless, these guidelines further state, "the issue of a lack of written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the

applicant has possession of the claimed invention" (*Id.* at 1105). The "Guidelines" continue:

> The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art. This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.

With further regard to the proposition that, as *original* claims, the claims themselves provide *in haec verba* support sufficient to satisfy the written description requirement, the Federal Circuit has explained that *in ipsis verbis* support for the claims in the specification does not *per se* establish compliance with the written description requirement:

> Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). *See also:* University of Rochester v. G.D. Searle & Co., 69 USPQ2d 1886 1892 (CA FC 2004).

Thus, an original claim may provide written description for itself, but it must still be an adequate written description, *which establishes that the inventor was in possession of the invention.*

In the instant case, claims 29-30 are broadly drawn to a genus of structurally and/or functionally disparate "antibodies to proteins comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO:1" or "antibodies to proteins comprising partial peptides of the amino acid sequence represented by SEQ ID NO:1 with the same or substantially the same

amino acid sequence".

However, as will be explained in further detail in the following paragraphs, the specification only adequately describes a polypeptide comprising SEQ ID NO:1 and therefore only adequately describes antibodies that specifically bind polypeptides comprising SEQ ID NO:1.

Notably, the specification discloses starting at page 7 the following about proteins that have "substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1":

> "Preferred examples of the protein comprising substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1 include proteins comprising substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO: 1 and having an activity substantially equivalent to that of the protein containing the amino acid sequence represented by SEQ ID NO: 1, etc."

Then, the specification discloses at page 9 the following about the polypeptides of the invention:

> "Examples of the protein used in the present invention include so-called muteins such as proteins comprising (1) (i) the amino acid sequence represented by SEQ ID NO: 1, of which at least 1 or 2 (e.g., about 1 to about 50, preferably about 1 to about 30, more preferably about 1 to about 10 and most preferably several (1 to 5)) amino acids are deleted, (ii) the amino acid sequence represented by SEQ ID NO: 1, to which at least 1 or 2 (e.g., about 1 to about 50, preferably about 1 to about 30, more preferably about 1 to about 10 and most preferably several (1 to 5)) amino acids are added, (iii) the amino acid sequence represented by SEQ ID NO: 1, in which at least 1 or 2 (e.g., about 1 to about 50, preferably about 1 to about 30, more preferably about 1 to about 10 and most preferably several (1 to 5)) amino acids are) inserted, (iv) the amino acid sequence represented by SEQ ID NO: 1, in which at least 1 or 2 (e.g., about 1 to about 50, preferably about I to about 30, more preferably about 1 to about 10 and most preferably several (1 to 5)) amino acids are substituted by other amino acids, or (v) a combination of these amino acid sequences".

Then at page 10, the specification discloses:

> "Where the amino acid sequence is inserted, deleted or substituted as described above, the position of its insertion, deletion or substitution is not particularly limited."

Additionally at page 11 the specification discloses the following about "partial peptides" of the invention:

> "The partial peptide of the protein used in the present invention may be any peptide as long as it is a partial peptide of the protein used in the present invention described above and preferably has the property equivalent to that of the protein used in the present invention described above.
> For example, there are used peptides containing, e.g., at least 20, preferably at least 50, more

> preferably at least 70, much more preferably at least 100, and most preferably at least 200 amino acids in the constituent amino acid sequence of the protein used in the present invention, etc.
>
> The partial peptide used in the present invention may be peptides containing the amino acid sequence, of which at least 1 or 2 (preferably about 1 to about 20, more preferably about 1 to about 10 and most preferably several (1 to 5)) amino acids may be deleted; peptides, to which at least 1 or 2 (preferably about 1 to about 20, more preferably about 1 to about 10 and most preferably several (1 to 5)) amino acids may be added; peptides, in which at least 1 or 2 (preferably about 1 to about 20, more preferably about 1 to about 10 and most preferably several (1 to 5)) amino acids may be inserted; or peptides, in which at least 1 or 2 (preferably about 1 to about 20, more preferably about 1 to about 10, much more preferably several and most preferably about 1 to about 5) amino acids may be substituted by other amino acids."

Notably, the specification does not provide any guidance as to which proteins would not be considered "substantially the same" as a protein comprising the amino acid sequence of SEQ ID NO":1, nor does it provide any guidance as to which proteins the amino acid sequence of SEQ ID NO:1 represents. As the polypeptides need only comprise a partial peptide of a protein comprising an amino acid sequence that is substantially the same as the amino acid sequence represented by SEQ ID NO:1 it is submitted that the genus of "proteins comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO:1" or "proteins comprising partial peptides of the amino acid sequence represented by SEQ ID NO:1" is inclusive of a structurally and functionally diverse genus of proteins. Notably, the claims do not require the "polypeptides" to have any particular function and therefore there can be no correlation of any particular identifying structural feature with any function of the claimed proteins. Thus, the specification fails to adequately describe these proteins, as a whole, because the skilled artisan could not immediately envision, recognize or distinguish as least most of its members from other proteins, as the specification fails to describe its members as sharing any particularly identifying (i.e., substantial) structural feature, which correlates with any one particularly identifying functional feature that is also shared by many, if not all, of those proteins.

In this case, the specification does not describe with any particularity the identifying structural and/or functional features of the "proteins comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO:1" or "proteins comprising partial peptides of the amino acid sequence represented by SEQ ID NO:1 with the same or substantially the same amino acid

sequence" and therefore, similarly does not adequately describe the genus of "antibodies" directed to these proteins.

For example, it is established in the art that there is a high degree of unpredictability in determining the structure of a given protein because a protein's structure is dependent on its given amino acid sequence and cannot be determined *a priori* and the function of a given protein is also highly unpredictable and variable and cannot necessarily be linked to a given structure. As evidenced by Jones (Pharmacogenomics Journal, 1:126-134, 2001), protein structure "prediction models are still not capable of producing accurate models in the vast majority of cases" (page 133, 3rd paragraph). Furthermore, Tosatto et al state, "the link between structure and function is still an open question and a matter of debate" (Current Pharmaceutical Design, 12:2067-2086, 2006, page 2075, 1st new paragraph). Therefore, the structure and function of the "proteins comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO:1" or "proteins comprising partial peptides of the amino acid sequence represented by SEQ ID NO:1" is highly unpredictable and as a consequence one of skill in the art would not recognize that the protein consisting of the amino acid sequence of SEQ ID NO:1 was representative of this structurally and functionally diverse genus of proteins.

Additionally, Skolnick et al. (*Trends in Biotechnology* 2000; **18**: 34-39), for example, discloses that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (see, e.g., the abstract; and page 34, *Sequence-based approaches to function prediction*). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see, in particular, the abstract and Box 2).

Finally, Bowie et al. (*Science* **257**: 1306-1310, 1990) teaches that an amino acid sequence encodes a message that determines the shape and function of a protein; and, that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function and carry out the instructions of the genome. Bowie et al.

teaches that the determination of protein structure from sequence data and, in turn, utilizing structural determinations to ascertain functional aspects of the protein is extremely complex (page 1306, column 1).

Thus, one skilled in the art would not accept the assertion, that the protein consisting of the amino acid sequence of SEQ ID NO:1 was representative of this structurally and functionally diverse genus of proteins that can have any function and any structure represented by SEQ ID NO:1, any structure substantially the same as SEQ ID NO:1 or any structure that comprises a partial peptide of SEQ ID NO:1.

Given the lack of particularity with which the genus of "proteins" is described, it is submitted that antibodies to proteins comprising amino acid sequences represented by SEQ ID NO:1, antibodies to proteins comprising substantially the same amino acid sequence represented by SEQ ID NO:1, and antibodies to proteins comprising partial peptides substantially the same as a partial peptide represented by SEQ ID NO:1 are inclusive of any antibody directed to any protein. Notably, the art is replete with antibodies that specifically bind proteins encompassed by this genus of proteins, including a multitude of antibodies that can be used to promote apoptosis and can be used as therapeutic agents for cancer. For example, Cuello et al (Can. Res., 61:4892-4900, 2001), describes an antibody (trastuzumab) to erbb2 that promotes apoptosis and is used therapeutically to treat cancer (see entire document, e.g., page 4892, right column, page 4894, left column and Figure 1). Therefore, the antibody trastuzumab is reasonably considered an antibody to which the claims are directed as the erbb2 polypeptide would be considered to be a protein represented by SEQ ID NO:1 and to comprise a partial peptide substantially the same as a partial peptide represented by SEQ ID NO:1. Notably the erbb2 polypeptide shares no substantial structural similarity with the protein consisting of SEQ ID NO:1.

Given the lack of particularity with which "proteins comprising the same or substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO:1" or "proteins comprising partial peptides of the amino acid sequence represented by SEQ ID NO:1" are described in the specification, it is submitted that the skilled artisan could not immediately envision, recognize or distinguish at least most of

the members of this genus, and therefore could not immediately envision, recognize or distinguish the antibodies to which the claims are directed. Therefore, the specification would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Osada et al (Can., 91:1156-1165, 2001).

Due to the indefinite nature of a protein comprising "substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO:1" and because polypeptides comprising partial peptides that are substantially the same to a partial peptide represented by SEQ ID NO:1 are broadly, but reasonably interpreted to include any protein, the claims are herein drawn to a composition comprising an antibody to a protein comprising any amino acid sequence.

Osada et al teach compositions comprising an antibody that specifically binds to phosphotyrosine amino acids (see entire document, e.g., page 1157, right column). Notably, the polypeptide consisting of the amino acid sequence of SEQ ID NO:1 contains multiple tyrosine residues, (see e.g., residue 70), and therefore one of skill in the art would immediately recognize that a phosphotyrosine antibody would bind proteins encompassed by the claims.

In this case, the compositions comprising an antibody of the prior art are

materially and structurally indistinguishable from the instantly claimed compositions. Therefore, absent a showing of any difference, the claimed compositions and the compositions disclosed by the prior art are deemed the same.

15. Claims 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Cuello et al (Can. Res., 61:4892-4900, 2001).

Due to the indefinite nature of a protein comprising "substantially the same amino acid sequence as the amino acid sequence represented by SEQ ID NO:1" and because polypeptides comprising partial peptides that are substantially the same to a partial peptide represented by SEQ ID NO:1 are broadly, but reasonably interpreted to include any protein, the claims are herein drawn to a composition comprising an antibody to a protein comprising any amino acid sequence.

Cuello et al teach compositions comprising an antibody to an erbb2 polypeptide (see entire document, e.g., page 4892, right column, page 4894, left column and Figure 1). Notably, as explained in the above rejection of the claims as lacking adequate written description the erbb2 polypeptide is broadly, but reasonably interpreted to be represented by SEQ ID NO:1 and comprise a partial peptide substantially the same as a partial peptide represented by SEQ IS NO:1.

In this case, the compositions comprising an antibody of the prior art are materially and structurally indistinguishable from the instantly claimed compositions. Therefore, absent a showing of any difference, the claimed compositions and the compositions disclosed by the prior art are deemed the same.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. Claims 29-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/584,183. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-14 of copending Application No. 10/584,183 are so substantially similar that for the most part, the claimed subject matter of the copending application anticipates the claimed subject matter of the instant application and any minor differences in the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The instant claims are described supra.

Claims 1-14 of copending Application No. 10/584,183 are drawn to compositions comprising antibodies to proteins comprising the same or substantially the same amino acid sequence as SEQ ID NO:1, which is 100% identical to SEQ ID NO:1 of the instant application (see alignment of SEQ ID NO:1 from 10/584,183 with the instant SEQ ID NO:1 attached as Exhibit A).

Accordingly, the claimed inventions are so substantially similar that for the most part, the claimed subject matter of the copending application anticipates the claimed

subject matter of the instant application and any minor differences in the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application.

18. Claims 29-30 are directed to an invention not patentably distinct from claims 1-14 of commonly assigned application 10/584,183. Specifically, although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth in the above provisional rejection of the claims on the ground of nonstatutory obviousness-type double patenting.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned copending application 10/584,183, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Conclusion

19. No claims are allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached on Monday through Friday 7:00 AM to 4:30 PM,

with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Stephen L. Rawlings, Ph.D.
Primary Examiner, Art Unit 1643

bd
July 13, 2007

Exhibit A

<!--StartFragment-->RESULT 1
US-10-584-183A-1
; Sequence 1, Application US/10584183A
; GENERAL INFORMATION:
; APPLICANT: Takeda Pharmaceutical Company Limited
; TITLE OF INVENTION: Preventing or treating agent for cancer
; FILE REFERENCE: P04-215PCT
; CURRENT APPLICATION NUMBER: US/10/584,183A
; CURRENT FILING DATE: 2006-06-23
; PRIOR APPLICATION NUMBER: JP 2003-427782
; PRIOR FILING DATE: 2003-12-24
; NUMBER OF SEQ ID NOS: 38
; SEQ ID NO 1
; LENGTH: 837
; TYPE: PRT
; ORGANISM: Homo sapiens
US-10-584-183A-1

Query Match 100.0%; Score 4433; DB 7; Length 837;
Best Local Similarity 100.0%; Pred. No. 0;
Matches 837; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Db          1 MLRTAMGLRSWLAAPWGALPPRPPLLLLLLLLLLLQPPPPTWALSPRISLPLGSEERPFL 60

Qy         61 RFEAEHISNYTALLLSRDGRTLYVGAREALFALSSNLSFLPGGEYQELLWGADAEKKQQC 120
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Qy        121 SFKGKDPQRDCQNYIKILLPLSGSHLFTCGTAAFSPMCTYINMENFTLARDEKGNVLLED 180
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Qy        241 VASAYIPESLGSLQGDDDKIYFFFSETGQEFEFFENTIVSRIARICKGDEGGERVLQQRW 300
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Qy        301 TSFLKAQLLCSRPDDGFPFNVLQDVFTLSPSPQDWRDTLFYGVFTSQWHRGTTEGSAVCV 360
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Db        781 PLDHRGYQSLSDSPPGSRVFTESEKRPLSIQDSFVEVSPVCPRPRVRLGSEIRDSVV 837<!--EndFragment-->
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